

K960677

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING  
SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF SMDA 1990.

**SECTION 6 - 510K SUMMARY**

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The Kangaroo® EntriStar Jejunal Feeding System is substantially equivalent to the BioSearch Dobbhoff GastroTrac Jejunal Feeding Tube (K900590), and the BioSearch Dobbhoff GastroTrac Jejunal Feeding System, (K900624), both currently manufactured by BioSearch and distributed by Sherwood Medical. Sherwood Medical Company will manufacture this product line.

The intended uses and components of the of Kangaroo Jejunal Feeding System are identical to the BioSearch Dobbhoff GastroTrac Jejunal Feeding Tube and System.

The Kangaroo Jejunal Feeding System is comprised of a gastrostomy tube and a jejunal feeding tube. The gastrostomy tube is identical to the BioSearch gastrostomy tube, and is a Foley-type of catheter. It is a dual lumen catheter with a retention balloon and outlet port at the the distal end. The proximal end has a female luer balloon inflation valve and an outlet adapter. The Gastrostomy Tube allows access to the jejunum by the Kangaroo Jejunal Feeding Tube. It is ethylene oxide sterilized to an SAL of  $10^6$ .

The Jejunal feeding tube is included with the system, and may also be packaged and sold separately. It consists of a polyether-based polyurethane and will be available in lengths ranging from 18" to 36", and in a range of tube diameters from 6 to 12 French.

Technological and performance characteristics of the Kangaroo Jejunal Feeding System are the same as that of the Biosearch predicate device; only the manufacturing site has been changed.

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